

Subpart D—Observational Research: Additional Protections for Children Involved as Subjects in Observational Research Conducted or Supported by EPA

SOURCE: 71 FR 6168, Feb. 6, 2006, unless otherwise noted.

§ 26.401 To what does this subpart apply?

(a) This subpart applies to all observational research involving children as subjects, conducted or supported by EPA. References to State or local laws in this subpart and in § 26.101(f) are intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments. This includes research conducted in EPA facilities by any person and research conducted in any facility by EPA employees.

(b) Exemptions at § 26.101(b)(1) and (b)(3) through (b)(6) are applicable to this subpart. The exemption at § 26.101(b)(2) regarding educational tests is also applicable to this subpart. However, the exemption at § 26.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

(c) The exceptions, additions, and provisions for waiver as they appear in § 26.101(c) through (i) are applicable to this subpart.

§ 26.402 Definitions.

The definitions in § 26.102 shall be applicable to this subpart as well. In addition, the following terms are defined:

(a) For purposes of this subpart, *Administrator* means the Administrator of the Environmental Protection Agency and any other officer or employee of the Environmental Protection Agency to whom authority has been delegated by the Administrator.

(b) *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, ab-

sent affirmative agreement, be construed as assent.

(c) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) *Parent* means a child's biological or adoptive parent.

(e) *Guardian* means an individual who is authorized under applicable State, Tribal, or local law to consent on behalf of a child to general medical care.

(f) *Observational research* means any research with human subjects that does not meet the definition of research involving intentional exposure of a human subject in § 26.202(a).

(g) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

§ 26.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review observational research covered by this subpart and approve only research that satisfies the conditions of all applicable sections of this subpart.

§ 26.404 Observational research not involving greater than minimal risk.

EPA will conduct or fund observational research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in § 26.406.

§ 26.405 Observational research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

If the IRB finds that an intervention or procedure presents more than minimal risk to children, EPA will not conduct or fund observational research that includes such an intervention or procedure unless the IRB finds and documents that:

(a) The intervention or procedure holds out the prospect of direct benefit